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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,463	07/26/1999	DAVID WYNICK	23016.0002	4323

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/230,463	WYNICK, DAVID	
	Examiner	Art Unit	
	Stephen Gucker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/28/05 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

4. Claims 18 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The only written descriptive support for the two instant claims is a single sentence found on page 12 of the instant specification, at the end of a portion of the disclosure describing the regeneration and cell survival ability of neurons in galanin knock-out transgenic mice: "Accordingly, the invention contemplates the use of a galanin agonist in the treatment of peripheral sensory neuropathy resulting, for example, from diabetes mellitus or trauma (such as that caused by traffic accidents.)" Therefore, there appears to be insufficient support for the treatment of

peripheral nerve damage wherein said peripheral nerve damage is treated by nerve regeneration, because the specification only provides support for the treatment of peripheral sensory neuropathy by nerve regeneration, which is a subgenus of the genus of peripheral nerve damage, and has a smaller breadth of scope than the genus of peripheral nerve damage. Furthermore, in regards to dependent claim 26, there is insufficient support in the specification for the dependent claim limitation "wherein the subject is human," because said claim limitation does not appear in the specification in context where the written description is made concerning the use of a galanin agonist in the treatment of peripheral sensory neuropathy wherein said treatment is by nerve regeneration. This is a new matter rejection.

5. Claims 18 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using galanin or N-terminal fragments of galanin, does not reasonably provide enablement for galanin agonists in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The disclosure teaches that galanin is a 29 amino acid neuropeptide and that the N-terminal portion of galanin is highly conserved between species. It is also disclosed that the prior art teaches that N-terminal fragments of galanin augment the effect of morphine, and this augmentation was known in the art as an agonistic effect. However, the specification does not provide an adequate written description, examples, or guidance to fully support the use of a galanin agonist for the following reasons. A galanin agonist is any compound that physiologically functions like

galanin, *regardless of its structure*. The only known galanin agonists of record at the time of the effective filing date of the instant application (7/24/96) were galanin itself and N-terminal fragments of galanin. The phrase "galanin agonist" includes any compounds, including non-peptides, that function like galanin. The instant methods encompass the use of any molecule that acts like galanin, therefore the limitation is functional rather than structural. The scope of the compounds used in the instant claims is therefore very broad, because the breadth is unfettered by any structural limitations. But, the relationship between function and structure for biological peptides is poorly understood. Even minor amino acid changes in a small peptide can bring about radical changes in function (see Rudinger, page 3 and Figure 1.2). Rudinger also states that "the significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study" (Rudinger, page 6). The breadth of the instant claims captures the use of any galanin agonist that is not envisioned or adequately supported by the specification, and even though the skill of the practitioner is high (Ph.D., M.D.), the full reasonable enablement of the claims, as Rudinger states, requires "painstaking experimental study," which is clearly beyond routine experimentation with no reasonable expectation of success, even for the skilled practitioner. In summation, and for the reasons given above, the specification does not provide an adequate description, any working examples, or sufficient guidance as to what compounds can be used in the methods as enabled galanin agonists, other than galanin and its N-terminal fragments.

6. Claims 18 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Luo et al. ("Luo") in view of Zhang et al. ("Zhang") for reasons of record and the following. Luo describes methods where galanin is administered to treat spinal cord hyperexcitability following sciatic nerve section which is peripheral nerve damage (abstract and pages 162-163). Luo does not teach that his method involves nerve regeneration or subjects other than rats. Zhang discloses that the findings in rat concerning galanin and peripheral nerve damage are valid and applicable in primates as well.

> "The main reason underlying our experiments was to explore whether the peptide galanin is upregulated in primates as it is in rats, since we have proposed that galanin may represent an endogenous analgesics compound activated after peripheral nerve lesions. Consequently, galanin agonists should represent new pharmacological tools to suppress chronic pain. The present findings show that, since some of these mechanisms also operate in monkey, this hypothesis is valid also for primates and provide a further impetus to test galanin or galanin agonists in humans" (page 375 of Zhang).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use galanin as a treatment following peripheral nerve damage as taught by Luo in primates, including humans, as taught by Zhang, for therapeutic purposes, including the treatment of peripheral nerve damage and pain resulting from such. Note that Zhang, in the context of peripheral nerve lesions (i.e. damage), makes the explicit suggestion that "galanin agonists should represent new pharmacological tools to suppress chronic pain" (underlining mine). Chronic pain in humans clearly implies the repeated use of galanin over a period of time that spans weeks, months, even years (the Zhang study was performed over a period of two weeks time). Therefore, the combination of the two references renders *prima facie* obvious a method to use galanin agonists to treat nerve damage, as taught by Luo, and to extend the use of galanin

agonists in humans to treat chronic pain from peripheral nerve lesions, as suggested by Zhang. The repeated, chronic use of galanin agonists in humans as suggested by the prior art to treat chronic pain would result in the galanin agonists promoting nerve regeneration, as required by the limitations of the instant claims. The promotion of nerve regeneration occurring by the chronic use of galanin to treat chronic pain is also supported by Applicant's arguments and affidavits that are directed to nerve regeneration occurring with the use of galanin over a period of time such as 24 hours and beyond, as measured by such phenomenon as retrograde axonal transport of galanin.

7. No claim is allowed.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached at (571) 272-0867. The fax phone number for this Group is currently (571)-273-8300.

SG

Stephen Gucker

August 4, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER